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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,888	08/07/2001	Thomas H. Barrows	016230-9004	9201

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MICHAEL BEST & FRIEDRICH, LLP
ONE SOUTH PINCKNEY STREET
P O BOX 1806
MADISON, WI 53701

EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/30/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,980

Applicant(s)

SUWELACK ET AL.

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 23-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicant's amendment A, filed 04/16/2003; and withdrawal of claim to small entity, filed 05/19/2003.

1. This application contains claims 23-36 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments

2. *Claim Rejections - 35 USC § 102*

The standing rejection:

Claims 1-5, 11-14, 16, 17, 20, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,486,593 ('593).

US '593 disclosed bioabsorbable and/or biodegradable solid fiber coated with polymer to form core-sheath structure (col.5, lines 1-5, 15-18; col.7, lines 7-12). The fibers may be used in monofilament form coated with other polymers (col.7, lines 28, 36). The polymers used for the invention (for both core and sheath) include d,l lactide, dioxanones, and anhydrides (col.16, lines 10-40). The polymers contain drugs such as growth factor and can be coated on the porous layer (col.19, lines 1, 10-15, 27-30). The

Art Unit: 1615

fibers can also comprise titanium, metal alloys such as chromium, cobalt, and molybdenum (col.19, lines 40-45). The fibers of the invention form solid core formed by melt extrusion, and then coated with polymer layer by solution dipping (col.5, 11-48; col.7, lines 20-27). The pores are formed by using chemical foaming agents (col.7, lines 21-26). The limitations of the above claims are met by the reference.

Applicant's argument:

US '593 does not teach a porous sheath coating applied to fiber after its formation.

Examiner's position:

The instant claim 1 is directed to article, and all the elements of the article are disclosed by the reference. The reference clearly disclosed that solid fibers (col.5, line 57) coated with other polymer layer that has pore that read on the instant invention. The polymers used in the invention are disclosed by the reference. The method of making included the same steps for forming the pores using the same materials, as claimed by applicant. The reference disclosed the device as a whole may be porous, but the filaments that form the device comprise solid core and porous sheath. The reference teaches coating of the fibers with the porous sheath and coating is applied by the same method as claimed by applicant, col.8, lines 31-52.

3. Claim Rejections - 35 USC § 103

The standing rejection:

Claims 1-22 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '593 in view of US 6,027,744 ('744) as applied to claims 6,7 and further, may or not in view of US 4,104,195 ('195) as applied to claims 18-19.

US '593 discloses bioabsorbable and/or biodegradable solid fiber coated with polymer to form core-sheath structure (col.5, lines 1-5, 15-18; col.7, lines 7-12). The fibers may be used in monofilament form coated with other polymers (col.7, lines 28, 36). The polymers used for the invention (for both core and sheath) include d,l lactide, dioxanones, and anhydrides (col.16, lines 10-40). The polymers contain drugs such as growth factor and can be coated on the porous layer (col.19, lines 1, 10-15, 27-30). The fibers can also comprise titanium, metal alloys such as chromium, cobalt, and molybdenum (col.19, lines 40-45). The fibers of the invention are formed in solid form by melt extrusion, and then coated with polymer layer by solution dipping (col.5, 11-48; col.7, lines 20-27). The pores are formed by using chemical foaming agents (col.7, lines 21-26).

US '593 does not teach the active agent as hair follicles, or as genetically engineered or encapsulated cells. The reference does not teach the particular foam forming agents.

US '744 disclosed living hair follicles incorporated in a biocompatible support structure (abstract; col.2, lines 65-66; col.3, lines 20-28). The support structure is rigid biodegradable and biocompatible includes ceramic or metal structure (col.2, lines 1-12,

Art Unit: 1615

46-47; col.16, lines 44-46). The support structure can be a polymer fibers coated by polyglycolic acid (col.6, lines 1- 37). Further the implant comprises nutrients and growth factors (col.1, lines 59-62; col.5, lines 60-67).

US '195 teaches foam forming agents that does not give off any corrosive, discoloring, unpleasant smelling or toxic decomposition products (col.1, lines 52-57). The foam forming agents disclosed by the reference include azodicarbonamide and urea dicarboxylic acid anhydride (col.2, lines 47-60).

It is well known in the implanting art to use genetically engineered cells and cell signaling molecule. However, applicants did not show superior and unexpected results in using the genetically engineered cells or the cell signaling molecules in particular.

It is also within the skill in the art to select the foaming material according to specific need, especially applicants provided no unexpected result to show the criticality of the azodicarbonamide and urea dicarboxylic acid anhydride as foaming agents.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide biocompatible biodegradable filament comprising core-sheath structure as disclosed by US '593, and add the hair follicles as an active agent into the filaments, as taught by US '744, motivated by the teaching of US '744 that the biodegradable polymer allows nutrients to diffuse to the cell and promote cell growth and proliferation, and replace the chemical foaming agent disclosed by US '593 by the azodicarbonamide or urea dicarboxylic acid anhydride as disclosed by US '195 motivated by the teaching of US '195 that these agents do not give off any corrosive, discoloring, unpleasant smelling or toxic decomposition products, with reasonable

Art Unit: 1615

expectation of success of the delivered filaments to implant hair follicles into a needy host.

Applicant's argument:

Applicant traverses the 103 rejection over US '744 and US '195, as applied to claim 18-19, by arguing that US '744 does not teach or suggest coating the individual fibers, and US '195 does not teach the use of porous sheath to coat solid filamentary core. The references alone or in combination do not teach the present invention.

Examiner's position:

US '744 is relied upon for teaching the incorporation of the hair follicles into the composition for generating new tissue as claimed in claim 6 and 7; and US '195 is relied upon for teaching the particular pore forming agents as claimed in claims 18 and 19. One cannot show nonobviousness by attacking the references individually where the rejections are based on combination of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose. See *In Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,599,552 and US 5,847,012 both disclosed biodegradable foam implant that can have a porous outer layer and deliver active agents and cells.

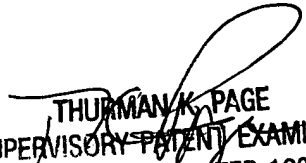
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)305-1235.

Isis Ghali
Examiner
Art Unit 1615


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600